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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/787,426  | 07/02/2001  | Kazutoshi Watanabe   | P20810              | 7478             |
| 7055  | 7590        | 06/04/2004           | EXAMINER            |                  |
| GREENBLUM & BERNSTEIN, P.L.C.<br>1950 ROLAND CLARKE PLACE<br>RESTON, VA 20191 |             |                      | TRUONG, TAMTHOM NGO |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1624                |                  |

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/787,426

**Applicant(s)**

WATANABE ET AL.

**Examiner**

Tamthom N. Truong

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-18 and 25-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-18, 25-38 and 40-42 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's amendment of 02-19-04 has been considered. The amended claims have overcome the previous rejection of 112/2<sup>nd</sup> on "*derivative*" and "*salt thereof*". Thus, said rejection is now withdrawn. The cancellation of claims 19-24 has also overcome the previous rejection of 112/1<sup>st</sup> on "*prophylactic treatment*". However, applicant's argument has not overcome the previous rejection of 112/1<sup>st</sup> on the broad scope of the method claims (e.g., a method of treating a disease caused by tau protein kinase 1). Therefore, said 112/1<sup>st</sup> rejection is maintained for method claims 13-15, 17, 18, 25, and 26.

Pending claims are 13-18, and 25-42. An update search yields the following new grounds of rejection.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 13-18, 25-38, and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claims 13, 17, 25, 27, 33, and 42 are indefinite because they recite moieties that "*may be substituted*" without substituents following said phrase. In the absence of the specific moieties intended to effectuate modification by "substitution" or attachment to

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the chemical core claimed, the term “substituted” renders the claims in which it appears indefinite in all occurrences wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

b. Claims 14-16, 18, 26, 28-32, 34-38, 40, and 41 are rejected as being dependent on claims 13, 25, 27, or 33.

c. Claims 25 and 26 seem to be substantial duplicates of claims 13 and 18 because they appear to have the same scope.

d. In the definition of “W”, when “W” represents “a nitrogen atom which may be substituted...”, it is unclear what the bond order (single or double) is between  $-N(R^4)$  and W.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of Enablement:** Claims 13-15, 17, 18, 25, and 26 remain rejected under 35

U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of

Alzheimer’s disease, does not reasonably provide enablement for the treatment of any disease

mediated by tau protein kinase 1. The specification does not enable any person skilled in the art

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to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The scope of claims 13 and 25 still covers the treatment for numerous diseases both known and unknown in the art. So far, the state of the art only associates tau protein kinase 1 with Alzheimer's disease. Therefore, it would require undue experimentation for the skilled clinician to practice the claimed method of treatment.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 27-29, 31-34, 36-38, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Spohr et. al.** (US 6,096,753) in view of **Spohr et. al.** (US 6,410,729 B1).

In US'753, Spohr et. al. disclose several compounds of substituted pyrimidinone (e.g., see column 138, compounds on lines 47, 21, 37, and 53). Said compounds are analogous to those of the instant formula (I) having the following substituents:

- i.  $R^1$  is  $-N(R^4)-W-R^5$  wherein W is a single bond, and  $R^5$  is an alkyl group substituted with a substituted phenyl group while  $R^4$  is hydrogen;
- ii.  $R^2$  is an alkyl group.

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The disclosed compounds differ from the claimed compounds by having  $-\text{CH}_3$  bonded a ring nitrogen atom. However, such a difference can be overcome by the subsequent teaching of Spohr et. al. (US'729). In US'729, the pyrimidinone compounds do not have substituents on the ring nitrogen atom. Because both sets of compounds share the same biological activity (i.e., treating diseases related to  $\text{TNF-}\alpha$ ,  $\text{IL-1}\beta$ , etc.), it is obvious that the biological activity remains the same whether or not the ring nitrogen is substituted.

Therefore, one of the ordinary skill in the art would have been motivated to modify the compounds of US'753 by not alkylating the ring nitrogen to obtain the claimed compounds because said compounds would have been expected to also treat diseases related to  $\text{TNF-}\alpha$ ,  $\text{IL-1}\beta$ , etc. Thus, at the time of the invention, it would have been obvious to make the compounds as claimed herein in view of the two teachings of Spohr et. al.

Note both patents of Spohr et. al. claim priority dates to their earlier provisional applications, which have the filing dates go back to 12-05-1996, and 06-13-1997.

### ***Claim Objections***


4. Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

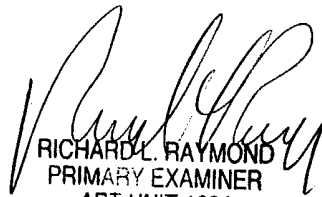
The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



T. Truong

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May 27, 2004



RICHARD L. RAYMOND  
PRIMARY EXAMINER  
ART UNIT 1624